A major challenge that exists for each of the, now 27, member states in the European Union is how to adopt a Directive whilst still retaining all the national characteristics within the particular field that is to be covered by that Directive. On the other hand, the adoption of a European Directive can provide a good opportunity to alter, or even abandon, national characteristics that have become outdated or are inappropriate or irrelevant.

One such Directive, known as the Clinical Trials Directive, was introduced in 2001 (2001/2001/EC), which required member states to adopt the principles of good clinical (research) practice where they had not already done so and, particularly, to establish research ethics committees. For some member states these had, in practice, been in operation for many years, but in others the ethical review procedure for clinical trials was vestigial and, for them, the implementation of this Directive presented a number of problems.

The European Forum for Good Clinical Practice (EFGCP) is a not-for-profit organisation, based in Brussels, which exists to promote, in its widest sense, and across the board, uniformly high standards for the conduct of clinical research. It is a confusing convention that, throughout the clinical research community, the word ‘research’ has been dropped from the phrase ‘good clinical research practice’, but that is what ‘good clinical practice’ (GCP) means, certainly in the context of this article.

One of the key features of the strategy of the European Forum for Good Clinical Practice (EFGCP) has always been to promote European values and principles in ethics across the EU member states and in international research. The standards against which this should be achieved were, by general agreement, set out by the Declaration of Helsinki of the World Medical Association, the International Conference on Harmonisation (ICH) process as it applied to good clinical practice (GCP) and, as far as Europe is concerned, were included within the Clinical Trials Directive.

All these important policy documents included reference to the structure and function of independent ethics committees established to provide the ethical review of all clinical trial protocols.

EFGCP operates through conferences, workshops and working parties and it was the EFGCP Ethics Working Party that felt that the advent of the Clinical Trials Directive presented a golden opportunity to ascertain exactly how this extremely important Directive, which was drafted to ensure that clinical trials throughout Europe were all conducted to the same high standard having been subjected to a proper ethical review, had in practice been interpreted in each of the 25 member states. We felt that reporting on the structure and function of research ethics committees in every member state was important, given that such a review had not been conducted previously by anyone else and that nobody seemed to know what was happening outside their own country in this regard.

We were particularly mindful that one of the functions of EFGCP is to observe the methods by which member states fulfil the various Directives of the European Commission that affect the conduct of clinical research to GCP standards. Thus it was in early 2005 that the EFGCP Ethics Working Party felt that the advent of the Clinical Trials Directive presented a golden opportunity to ascertain exactly how this extremely important Directive, which was drafted to ensure that clinical trials throughout Europe were all conducted to the same high standard having been subjected to a proper ethical review, had in practice been interpreted in each of the 25 member states. We felt that reporting on the structure and function of research ethics committees in every member state was important, given that such a review had not been conducted previously by anyone else and that nobody seemed to know what was happening outside their own country in this regard.

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Working Party recognised that the ethical review processes in the various member states varied widely and that, in the context of multi-national research, it was not easy to be sure that ethical review had been consistent across the whole of Europe. The Working Party even wondered whether the differences between operational policies in the various member states might interfere with the aims of the Directives. Furthermore, whereas a sponsor could be reasonably confident that it understood the ethical review process that operated in the member states in which it regularly conducted research, it was sometimes difficult to gain access to the ethical review process in other member states in which it might wish to conduct research in the future.

A subgroup of the EFGCP Ethics Working Party was established, specifically to ascertain in detail exactly what were the structures and functions of research ethics committees across the 25 member states of the EU. The nine members of the subgroup came from eight different member states, which made it easy for us to share the work that had to be done. In practice, we acknowledged that Luxembourg relied wholly on Belgian legislation in this regard, and, because much clinical research emanates from, or is conducted within, Switzerland and Norway, we took a pragmatic decision to add these two countries to our project.

The differences we discovered were widespread. For example, roughly half the member states specify that an application should be made to an ethics committee by the sponsor, whereas the other half specify that it should be made by the chief investigator. Another example revealed the different methods by which a single opinion is obtained for a multi-site application within any given member state: some countries designate which committee out of several, whereas others only have one committee for the whole country anyway. The most striking differences arose in the areas of training for members of research ethics committees and of quality assurance, assessment and accreditation of such committees.

We were particularly interested in the independence of research ethics committees (RECs). For some time there has been concern within the research ethics community that the equivalent bodies to RECs in the USA are institutional review boards (IRBs) which, by definition, cannot be truly independent as they are based on specific, usually academic, institutions. In general, we found that RECs in Europe are constituted in such a way as to ensure that the independence of committees and of individual members is safeguarded, but there were some member states that clearly followed the institution-based model. However, where appropriate safeguards are in place, even institutional review boards can demonstrate that they operate independently; but such safeguards are not always there. It is therefore important that bodies such as the WMA and EFGCP strive to ensure that any committee conducting ethical reviews of research projects involving human subjects is truly independent in its constitution and in its decision-making processes.

EFGCP hopes that this report published in January 2007 will be of practical use to sponsors, investigators, regulators and those that have responsibility for setting research ethics committees up and subsequently approving them. The report could not have been produced without the invaluable help and co-operation provided by the many persons within the member states who have provided information that has been gathered together.

Finally, the development of the research ethical review process in Europe is inevitably in a state of flux. Recent entrants into the EU have clearly striven to achieve the requirements of the Directive and of its recent companion on GCP (2005/28/EC). New candidates for EU membership, notably Bulgaria and Romania, have yet to demonstrate their adoption of these Directives but no doubt they will. Even within well-established member states we found that the detail of how ethical review was actually being conducted was constantly changing. However, by referring to the relevant websites for the various countries, readers will be able to check for themselves the exact situation pertaining at any given time. The challenge of safeguarding research subjects is a highly responsible one for research ethics committees throughout the world. Our awareness of the importance of this challenge should go some way towards ensuring that the highest possible standards of clinical research practice are attained.
References